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Original Article

Patient-Reported Outcomes in Middle Ear and Active Transcutaneous Bone Conduction Hearing Implants

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OBJECTIVE: This study used questionnaires to examine the patient-reported satisfaction with 2 hearing implant devices to determine the level of overall satisfaction with the devices, which, if any, factors predicted good or poor perceived outcomes, or whether there were any specific aspects of the devices where dissatisfaction was apparent.

METHODS: A post-treatment questionnaire survey of 39 adult patients who had received a Vibrant Soundbridge (VSB) or Bonebridge (BB) hearing implant, with at least 3 months of follow-up, was conducted using the Glasgow Benefit Inventory (GBI) and Hearing Device Satisfaction Scale (HDSS). Satisfaction scores were compared to pre- and post-operative audiologic outcomes. The correlation between GBI and HDSS scores was also examined.

RESULTS: A total of 28 of the 39 patients (72%) responded: 13 with a BB and 15 with a VSB at a mean of 13 months after implantation. The overall mean total GBI score was 30, with no significant differences across the groups. The responders generally reported that they were "satisfied" across most domains of the HDSS. In the study, 25 of the 28 responders were largely satisfied with their devices but 3 respondents were not. Two were known non-users, while one used the device but did not gain the benefit expected. It is instructive to note that all of these dissatisfied recipients were close to the manufacturer recommended limits for implantation of their respective devices at the time of surgery.

Certain themes were identified within the patients' responses, indicating common aspects where satisfaction was poorer.

CONCLUSION: This series of 28 implant recipients demonstrates high levels of satisfaction with implantable hearing devices across 2 different validated questionnaires. Implant teams could exercise caution and manage patient expectations if the patients are close to the recommended limits of a particular device.

KEYWORDS: Bonebridge, Vibrant Soundbridge, transcutaneous, quality of life

INTRODUCTION

The hearing implant service in our hospital first started offering semi-implantable active middle ear implants (MEIs) in the form of Vibrant Soundbridge (VSB) (Med-El, Innsbrück, Austria) in 2011. The VSB consists of an implanted device and an external sound processor. The implant comprises a magnet, a coil, and electronics package placed superior to the mastoid with a conductor link cable connected to the floating mass transducer (FMT) in the middle ear. The sound processor is attached to the implanted part by a magnet and provides the power and signal to the implant. We subsequently offered the semi-implantable bone conducting implant Bonebridge (BB) (Med-El, Innsbrück, Austria) implants from the time of their entry to the UK market in 2012. This implant differs from the VSB with the much larger bone conducting floating mass transducer (BC-FMT) attached directly to the rest of the device by a malleable connection. A circular defect is created in the bone for the BC-FMT, which is screwed to the temporal bone directly, with sound transmission through the screws to the temporal bone. Both devices have a similar external sound processor in common. Anecdotally, some recipients reported greater satisfaction with their implant than others did. This study was designed to examine

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our patients' satisfaction with their devices and whether there were any consistent patterns related to good or poor satisfaction.

MATERIALS AND METHODS

Between 2011 and 2017, 40 patients underwent surgery for implantation of a VSB or BB in our tertiary referral center. Their ages ranged from 14 to 81 years. The single patient aged under 18 was excluded, and the remaining 39 patients were invited to take part in a questionnaire survey. Letters inviting them to take part were sent at least 3 months post-operatively. Patients who were known non-users of the device were included. If happy to take part, respondents were asked to complete the Glasgow Benefit Inventory (GBI) and Hearing device satisfaction scale (HDSS) questionnaires in English. Formal ethical approval for this study was not required by our Local Research Ethics Committee as no change to patients' treatment was caused by the administration of questionnaires.

The GBI is a validated post-intervention scoring system, which uses an 18-question questionnaire. It was originally developed for use in ENT surgery and has been widely used to examine a number of different interventions. Respondents score questions between 1 and 5. Glasgow Benefit Inventory scores were calculated using the standard method described by the original authors to give general, social, physical, and total scores. The resulting scores may range from −100 to +100, depending on the level of patient satisfaction, where 0 is a neutral response and positive scores indicate improvement in patient satisfaction. Where patients did not provide a response to a question, the calculation of resulting scores is not possible. This occurred for 5 questions across the entire cohort, in 3 questions for 1 patient. As GBI calculations require all questions to be answered, it was assumed that the patients had no positive or negative opinion, and a score of 3 was recorded in place of the absent response.

The HDSS utilizes a 21-question questionnaire (Figure 1) and is specifically written to examine satisfaction with hearing aids or hearing implants. It is less widely used but has previously been used in a number of studies for examining VSB and BB satisfaction.[1-8] Patient responses may be "very satisfied," "satisfied," "sometimes satisfied/dissatisfied," "dissatisfied," "very dissatisfied," or "does not apply." The HDSS questionnaire has not been validated, but its questions are particularly suited to implants such as those under investigation. The authors were unable to retrieve any instructions on questionnaire administration or analysis in the published articles identified above. Analysis of this score was not possible using the verbal responses, which were therefore converted into numerical scores from −2 to +2 for "very dissatisfied" to "very satisfied," respectively.

Patients' pure tone and speech audiogram outcomes were also reviewed and compared to their satisfaction scores using Pearson's rank correlation coefficient.

Mean calculations for groups and subgroups were carried out using Microsoft Excel (version 16.38, Microsoft Corporation, Redmond, WA, USA). Examination of the correlation between GBI scores and half-optimal speech reception thresholds and between GBI and HDSS scores was carried out using the R statistical software package (version 4.0.3).[9]

RESULTS

In total, 28 of the 39 patients who were contacted responded (72%), of whom 13 had a BB and 15 had a VSB. The non-respondents included 4 BB recipients and 7 VSB recipients. Eighteen of the respondents were female and 10 were male, from a total of 26 female and 14 male implant recipients. Two of the VSB users were implanted bilaterally at the time of administration of the questionnaire. The respondents' ages ranged from 18 to 81 years in the BB subgroup and 40 to 78 years in the VSB subgroup.

The time between implant surgery and administration of the questionnaires ranged from 3.4 to 38 months (mean 13.1 months).

Soundbridge placement was on the incus long process in 5 respondents, incus short process (latterly when couplers for this location became available) in 3, stapes head in 3, oval window in 2, and round window in 2.

The most common indications for implantation were sensorineural and mixed hearing losses with chronic otitis externa or infection. Two of the BB recipients who responded had received their implant to treat single-sided deafness (SSD).

Two respondents were known to have become non-users of their devices. Both had received VSB devices. One had absent stapes arch and incus, and bone erosion in the region of the round window, likely due to previous cholesteatoma, requiring device placement on the round window. The other had no obvious abnormality and underwent implantation onto the short process of the incus without difficulty. Both patients had poor bone conduction thresholds pre-operatively but were within the manufacturer's audiological criteria for the VSB. Post-operatively, both patients were found to have a slight deterioration in their bone conduction thresholds. This meant that they were now slightly outside audiological criteria for the device in some frequencies. Neither of these 2 patients found the device beneficial. Unsurprisingly, both patients gave the poorest scores on GBI. One of these patients also failed to respond to many of the questions in the HDSS, probably reflecting her non-use of the device.

A third VSB recipient scored poorly on HDSS. Her hearing was within the manufacturer's recommended criteria pre-operatively but was among the poorest of the study group. She appeared to have no change in her unaided audiometry post-operatively, and her speech audiometry results were better than those predicted pre-operatively in testing using a bone conducting hearing device (BCHD) on soft headband. Her dissatisfaction may represent either hearing on the borderline for suitability or excessively high patient expectations rather than a suboptimal outcome.

Finally, 1 BB recipient gave more neutral GBI and HDSS scores than did most of the cohort. He did not appear to have had any adverse outcomes, and the device appears to be giving the expected hearing result. This patient had previously received a bone conducting hearing device on the opposite side. This may reflect the limited benefit of a second device, whether a hearing aid or an implant, compared with the benefit of the initial device.

Vibrant Effectiveness and Reliability Study

HEARING DEVICE SATISFACTION SCALE

Details at time of observation	
Participant Code	_____
Date	___ ___ ___ (mm dd yy)
Age of the user	___ years
Daily use	___ hours per day
___	weeks after the first fitting
Clinic	_____
Type of hearing device currently used	_____

Please rate your level of satisfaction with the following features of the hearing device:

How satisfied are you with the following features	very satisfied	satisfied	sometimes satisfied/ dissatisfied	dissatisfied	very dissatisfied	does not apply
1. Overall fit or comfort	☐	☐	☐	☐	☐	☐
2. Visibility to others	☐	☐	☐	☐	☐	☐
3. Sound quality of my own voice	☐	☐	☐	☐	☐	☐
4. Speech in background noise	☐	☐	☐	☐	☐	☐
5. Clearness of sound and tone	☐	☐	☐	☐	☐	☐
6. Whistling, feedback, buzzing	☐	☐	☐	☐	☐	☐
7. Overall sound quality	☐	☐	☐	☐	☐	☐
8. Naturalness of speech	☐	☐	☐	☐	☐	☐
9. Cosmetics (appearance)	☐	☐	☐	☐	☐	☐
10. Handling, manipulation of device	☐	☐	☐	☐	☐	☐
11. Cleaning and maintenance	☐	☐	☐	☐	☐	☐
12. Reliability	☐	☐	☐	☐	☐	☐
13. Improvement of hearing in general	☐	☐	☐	☐	☐	☐
14. Improvement in quality of life	☐	☐	☐	☐	☐	☐
15. Sound when you chew	☐	☐	☐	☐	☐	☐
16. Telephone use	☐	☐	☐	☐	☐	☐
17. Repair time (n/a)	☐	☐	☐	☐	☐	☐
Sound quality when listening						
18. To music	☐	☐	☐	☐	☐	☐
19. Via the telephone	☐	☐	☐	☐	☐	☐
20. To the radio	☐	☐	☐	☐	☐	☐
21. To the television	☐	☐	☐	☐	☐	☐

Figure 1. Hearing Device Satisfaction Scale Questionnaire (HDSS).

Hearing Device Satisfaction Score

In certain cases, patients failed to respond or responded frequently with "does not apply." This was particularly seen for question 17 (repair time) by a significant margin. This was seen as a positive outcome suggesting good reliability of the device and little need for repair. Question 16 (telephone use) and question 19 (sound quality when listening via the telephone) were also often given a "does not apply" response suggesting that patients were not using their devices with their telephones.

Four questions from the HDSS questionnaire also scored poorly overall in the responses compared with other questions. When converted into numerical scores: question 16 (telephone use) (0.14), question 19 (sound quality when listening via the telephone) (0.3), question 4 (speech in background noise) (0.36), and question 5 (clarity of sound and tone) (0.64). Once again, responses relevant to telephone use showed poor satisfaction, which, although positive, were just above 0. The poorer responses for questions 4 and 5 were surprising. The number of respondents scoring questions 4 and 5 as "dissatisfied" or "very dissatisfied" was small, but this affected the overall response to this question. The dissatisfied respondents were principally patients whose hearing was near the limit recommended for their device and included the non-users. As a significant number of respondents gave the "sometimes satisfied/dissatisfied" response, the overall score for these domains was poorer than the score for most other domains (Table 1).

There was almost no difference in the overall HDSS scores when the VSB and BB groups were compared. The responses for question 17 (repair time) were higher for the VSB group than for the BB group. The responses for question 5 (clarity of sound and tone) and question 21 (sound quality when listening to the television) were higher for the BB group than for the VSB group. These differences were not felt clinically significant, and the number of respondents was so small that subgroup analysis was unlikely to provide further insights.

Questions related to other aspects of the devices showed very good satisfaction in general. Question 1 (overall fit or comfort) (1.46), question 10 (handling, manipulation of the device) (1.41), question 11 (cleaning and maintenance) (1.4), question 12 (reliability) (1.37), and question 2 (visibility to others) (1.36) clearly showed high satisfaction levels of patients when compared with other questions. All these questions particularly referred to the external sound processors that are simple for patients to interact with and to place correctly on the underlying implant.

The range of scores possible by converting the HDSS responses to a number was small, and so a meaningful comparison was difficult. Looking at the scores given by individual patients, these ranged from −1.1 to +1.8. The overall mean score of all patients was 0.95, which equates approximately with a "satisfied" response. Only 3 patients gave overall scores lower than 0. Two of these were non-users of VSB devices, both having pre-operative hearing on the borderline for suitability for the device and suffering a small but significant reduction in bone conduction thresholds post-operatively. The third patient also received a VSB but had hearing well within the manufacturer's recommended range and appeared to have good pure tone and speech audiometry results on post-operative testing. The reason for their dissatisfaction is unclear.

Table 1. Responses to Hearing Device Satisfaction Score Questionnaire

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21
Total score	41	38	31	10	18	22	22	32	37	38	35	37	32	32	25	3	9	22	7	23	22
Mean score	1.46	1.36	1.11	0.36	0.64	0.88	0.79	1.19	1.32	1.41	1.4	1.37	1.19	1.19	1.04	0.14	0.9	0.81	0.30	0.85	0.85
BB score	20	18	17	6	12	8	13	17	18	20	19	17	15	16	11	1	4	10	3	12	15
VSB score	21	20	14	4	6	14	9	15	19	18	16	20	17	16	14	2	5	12	4	11	7

Key: −2 (very dissatisfied) to +2 (very satisfied).

Glasgow Benefit Inventory

When individual questions in the GBI questionnaire were examined, none appeared to show any clearly positive or negative result when compared with the other questions.

The GBI scores were calculated for all respondents, and their mean, range, and 95% CI values were as follows: GBI general mean 38.1 (range 95.8- to 100, 95% CI: ±16.2), GBI social mean 14.3 (range 100 to −16.7, 95% CI: +/- 9.8), GBI physical mean 11.3 (range 100 to −66.7, 95% CI: ±14.9), and GBI total mean 29.7 (range 83.3 to −69.4, 95% CI: ±12.7). The lowest score in the GBI physical calculation was an outlier, due to a patient who had medical problems unrelated to his hearing loss or implant. Scores were calculated separately for the 2 different devices (Table 2); little difference was seen between the 2 groups, except in the case of social scores, where VSB recipients scored their satisfaction more highly than those receiving BB devices. We postulate that this may be because of the greater gain possible with the VSB, allowing patients with poorer hearing to receive this device and to benefit from greater hearing improvement.

Calculations were also carried out with the 2 device non-users removed, so that scores reflecting actual users could be reviewed. The following GBI scores were found: GBI general mean 45.8, GBI social mean 14.1, GBI physical mean 14.1, and GBI total mean 35.3. Unsurprisingly, the scores showed an improvement with non-user scores removed from calculations.

Correlation Between PROMs and Audiological Outcomes

Audiological data were incomplete, principally for the earliest patients implanted who did not undergo all of our current standard schedule of pre-operative audiological assessments or whose data could not be retrieved from the audiology systems. Two patients receiving a BB for SSD had no pre-operative hearing in the implanted ear, so comparison of audiometric outcomes was therefore not possible. Overall, this meant that 3 patients could not be included in calculations based on the audiometric calculations.

No clear correlation between improvement in speech audiometry and GBI scores could be identified. These relationships were examined using the Pearson correlation coefficient, which was calculated for post-operative half-optimal speech reception threshold compared to GBI general score, GBI total score and between change in half-optimal speech reception threshold compared to GBI total score. The results for these tests were −0.151 (95% CI: −0.496 to 0.235), −0.152 (95% CI: −0.497 to 0.234), and −0.0448 (95% CI: −0.432 to 0.357), respectively. All values were near 0, with 95% CI above and below 0, showing no relationship between these outcomes.

Correlation Between PROM Questionnaires

The HDSS questionnaire has not been previously validated. We also examined the results from our patients to compare satisfaction according to the GBI total and HDSS outcomes we received. This demonstrated a Pearson correlation coefficient of 0.753 (95% CI: 0.529-0.879) and *P*-value of <.0001 (Figure 1). This suggests that HDSS closely reflects the outcome of GBI in our group of patients.

Table 2. Calculated GBI Values for All Patients, Recipients of VSB and BB

	General	Social	Physical	Total
All Devices	38.1	14.3	11.3	29.7
VSB	36.4	17.8	8.9	28.7
BB	40.1	10.3	14.1	30.8

DISCUSSION

GBI has been used widely in ENT surgery and in a large number of interventions. Previous articles have been published giving GBI outcomes for VSB in all FMT placements[10-12] as well as specifically in round window vibroplasty,[13] BB used in all causes of hearing loss[11,14] and in SSD specifically,[15] BCHD,[11,15-17] Esteem,[11] and conventional hearing aids.[10] An interesting systematic review was also published specifically comparing the GBI outcomes between a number of ENT interventions, including BCHD and MEI.[18] Unfortunately, the heterogeneity between the studies of BCHD was high, and so meta-analysis could not be carried out, but the mean GBI total score for the papers examining MEI outcomes was 16.3 (95% CI: 10.4-22.1).

A summary of the GBI outcomes for similar hearing devices cited in the publications above can be seen in Table 3.

Hearing Device Satisfaction Scale has been less widely used in the published literature. Böheim et al.[5] described its use in VSB implantation on the round window, and Baumgartner et al.[3] described its use in a larger multicenter study. These papers describe a pre- and post-implantation percentage satisfaction score in the results; however, in their paper, the authors do not explain how they arrived at this score. It was interesting to see that in our group of patients, the HDSS score correlated well with the long-established GBI score.

At the time the department first offered VSB, the sound processor provided with the device did not have any built-in facility to communicate with mobile or landline telephones using Bluetooth. It also did not include a loop induction system in the device. The same device was the standard sound processor at the time of release of the BB device. A new sound processor, called Samba, was launched at the time of the launch of the current model of VSB in

Table 3. Comparison of Mean GBI Total Scores, ± Standard Deviation (SD) or 95% Confidence Interval (CI), Where Available, for Hearing Devices in Different Studies

	VSB	BB	BCHD	Hearing Aid
Jones et al.	28.7 ± 95% CI: 21.5, n = 15	30.8 ± 95% CI: 15.3, n = 13		
Ihler et al.[10,14]	38.3 ± SD: 32.3, n = 10	32.4 ± SD: 13.5		24.8 ± SD: 22.2, n = 12
Monini et al.[11]	36.5, n = 10	35.2, n = 4	23, n = 27	
Ho et al.[16]			38 95% CI: ± 6, n = 71	
Saroul et al.[15]			17.4, n = 24	
Zwartenkot et al.[12]	20.1 ± SD: 16.0, n = 33			
Lassaletta et al.[13]	35 ± SD: 17.0, n = 12			
Arunachalam et al.[17]			31 ± 95% CI 9, n = 51	

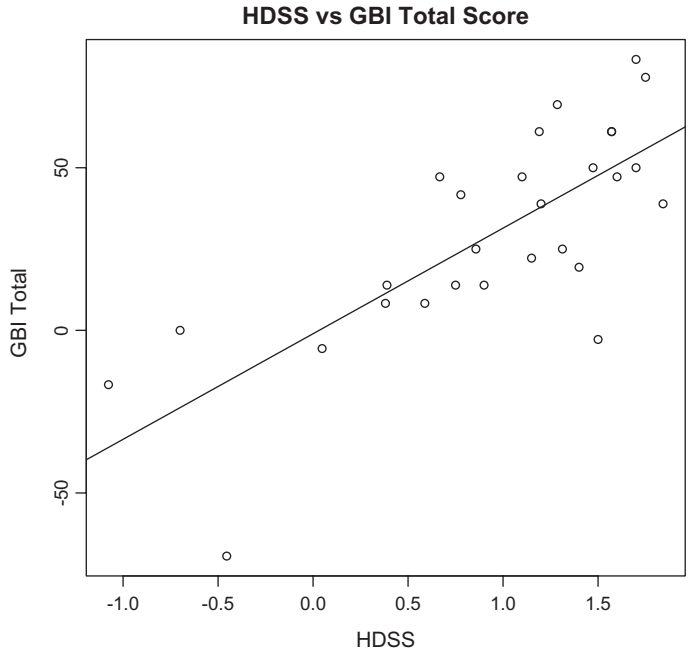

Figure 2. Plot of HDSS score against Glasgow Benefit Inventory (GBI) total.

2015. This does allow connection to Bluetooth and loop systems via an additional device. The Siemens miniTek device (Siemens AG, Munich, Germany) is included for patients undergoing implantation with either device in the UK. All of our patients who underwent surgery since 2015 have received the new device and will have the miniTek. Some of the earlier patients may also have required a newer sound processor, which also functions with the earlier model of VSB implants. It does not appear that the satisfaction scores in HDSS differ greatly between the earlier and later patients. This may reflect difficulties the audiologists have had in pairing the miniTek with patients' phones or the dissatisfaction with the requirement to carry a second device so that their implants will work with their phones.

The overall satisfaction scores on both questionnaires were positive. The mean overall score on HDSS was 0.95, which would equate to an overall "satisfied" response. The scores on GBI were all positive, and the results in all domains were comparable with those in similar studies. Further work with a larger patient cohort may allow us to assess for the evidence of correlation between subgroups and quality-of-life measures.

Two of the patients who took part in this study were non-users of their MEI device. In both cases, their pre-operative hearing was within the recommended limit; however, their bone conduction thresholds deteriorated only slightly per-operatively, taking them outside recommended thresholds. This serves as a reminder that surgery or other causes may result in progression of hearing loss. When considering patients at or near the limit of the implant for surgery, it is important to consider this possibility and to counsel the patient appropriately. It was unsurprising that the 2 non-users gave the poorest satisfaction scores.

Although some complications were seen and some implant recipients became non-users, the overall levels of satisfaction with both VSB and BB were high. This series compares well with other similar series and demonstrates that these devices have a place in rehabilitation of patients with hearing loss.

The group of patients who scored most poorly in both questionnaires were those whose hearing was near the limits of the manufacturer's recommendations for suitability. Patients such as this should be considered carefully and counseled pre-operatively to ensure that their expectations of the device are realistic.

Themes of poorer satisfaction with the devices were found with the HDSS question that related to telephone use. We believe this may be due to the difficulties with lack of connectivity using either Bluetooth or loop induction in earlier sound processors and problems with connection via Bluetooth in more recent devices. We hope that this will be addressed in future updates to the sound processor for both devices.

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REFERENCES

1. Luetje CM, Brackman D, Balkany TJ, et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: a prospective controlled multicenter study. *Otolaryngol Head Neck Surg*. 2002;126(2):97-107. [CrossRef]
2. Uziel A, Mondain M, Hagen P, Dejean F, Doucet G. Rehabilitation for high-frequency sensorineural hearing impairment in adults with the Symphonix Vibrant Soundbridge: a comparative study. *Otol Neurotol*. 2003;24(5):775-783. [CrossRef]
3. Baumgartner WD, Böheim K, Hagen R, et al. The Vibrant Soundbridge for conductive and mixed hearing losses: European multicenter study results. *Adv Otorhinolaryngol*. 2010;69:38-50. [CrossRef]
4. Lim LHY, Del Prado J, Xiang L, Yusof ARB, Loo JHY. Vibrant Soundbridge middle ear implantations: experience at National University Hospital Singapore. *Eur Arch Otorhinolaryngol*. 2012;269(9):2137-2143. [CrossRef]
5. Böheim K, Mlynski R, Lenarz T, Schlögel M, Hagen R. Round window vibroplasty: long-term results. *Acta Otolaryngol*. 2012;132(10):1042-1048. [CrossRef]
6. Sprinzl G, Lenarz T, Ernst A, et al. First European multicenter results with a new transcutaneous bone conduction hearing implant system: short-term safety and efficacy. *Otol Neurotol*. 2013;34(6):1076-1083. [CrossRef]
7. Baumgartner WD, Hamzavi JS, Böheim K, et al. A new transcutaneous bone conduction hearing implant: short-term safety and efficacy in children. *Otol Neurotol*. 2016;37(6):713-720. [CrossRef]

8. Vickers D, Canas A, Degun A, et al. Evaluating the effectiveness and reliability of the Vibrant Soundbridge and Bonebridge auditory implants in clinical practice: study design and methods for a multi-centre longitudinal observational study. *Contemp Clin Trials Commun*. 2018;10:137-140. [CrossRef]
9. R Core Team. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2016.
10. Ihler F, Bewarder J, Blum J, Matthias C, Canis M. Long-term functional outcome and satisfaction of patients with an active middle ear implant for sensorineural hearing loss compared to a matched population with conventional hearing aids. *Eur Arch Otorhinolaryngol*. 2014;271(12):3161-3169. [CrossRef]
11. Monini S, Bianchi A, Talamonti R, et al. Patient satisfaction after auditory implant surgery: ten-year experience from a single implanting unit center. *Acta Otolaryngol*. 2017;137(4):389-397. [CrossRef]
12. Zwartenkot JW, Hashemi J, Cremers CWRJ, Mulder JJS, Snik AFM. Active middle ear implantation for patients with sensorineural hearing loss and external otitis: long-term outcome in patient satisfaction. *Otol Neurotol*. 2013;34(5):855-861. [CrossRef]
13. Lassaletta L, Calvino M, Sánchez-Cuadrado I, et al. Pros and cons of round window vibroplasty in open cavities: audiological, surgical, and quality of life outcomes. *Otol Neurotol*. 2015;36(6):944-952. [CrossRef]
14. Ihler F, Volbers L, Blum J, Matthias C, Canis M. Preliminary functional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss. *Otol Neurotol*. 2014;35(2):211-215. [CrossRef]
15. Saroul N, Akkari M, Pavier Y, Gilain L, Mom T. Long-term benefit and sound localization in patients with single-sided deafness rehabilitated with an osseointegrated bone-conduction device. *Otol Neurotol*. 2013;34(1):111-114. [CrossRef]
16. Ho EC, Monksfield P, Egan E, Reid A, Proops D. Bilateral bone-anchored hearing aid: impact on quality of life measured with the Glasgow Benefit Inventory. *Otol Neurotol*. 2009;30(7):891-896. [CrossRef]
17. Arunachalam PS, Kilby D, Meikle D, Davison T, Johnson IJ. Bone-anchored hearing aid quality of life assessed by Glasgow Benefit Inventory. *Laryngoscope*. 2001;111(7):1260-1263. [CrossRef]
18. Hendry J, Chin A, Swan IR, Akeroyd MA, Browning GG. The Glasgow Benefit Inventory: a systematic review of the use and value of an otorhinolaryngological generic patient-recorded outcome measure. *Clin Otolaryngol*. 2016;41(3):259-275. [CrossRef]